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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,931	11/12/2001	Carla H. Kuhner	HER-0048	7846

7590 11/15/2004
Patrick J. Farley, Ph.D.
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EXAMINER

KOSAR, ANDREW D

ART UNIT PAPER NUMBER

1654

DATE MAILED: 11/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/005,931

Applicant(s)

KUHNER ET AL.

Examiner

Andrew D Kosar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-37 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims 1-37 are pending. Claims 1-37 require restriction.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-18, drawn to antimicrobial compositions comprising formula (I) and a second antimicrobial compound, classified in various classes and subclasses (530/300, 331, 330, 345; 564/152, 153; 554/112, 111, 106, 57, 58, 56, 35; 540/316; 534/721, 638, 563, 152; 510/333; 514/2, 9; 424/76.8, 78.02, 187, 404; 536/16.8).
- II. Claims 19-36, drawn to antimicrobial compositions comprising formula (II) and a second antimicrobial compound, classified in various classes and subclasses (530/300, 331, 330, 345; 564/152, 153; 554/112, 111, 106, 57, 58, 56, 35; 540/316; 534/721, 638, 563, 152; 510/333; 514/2, 9; 424/76.8, 78.02, 187, 404; 536/16.8).
- III. Claim 37, drawn to a method of preventing, inhibiting, or terminating the growth of at least one microbe with a compound of formula (I), classified in various classes and subclasses (530/300, 331, 330, 345; 564/152, 153; 554/112, 111, 106, 57, 58, 56, 35; 540/316; 534/721, 638, 563, 152; 510/333; 514/2, 9; 424/76.8, 78.02, 187, 404; 536/16.8).
- IV. Claim 37, drawn to a method of preventing, inhibiting, or terminating the growth of at least one microbe with a compound of formula (II), classified in various classes and subclasses (530/300, 331, 330, 345; 564/152, 153;

554/112, 111, 106, 57, 58, 56, 35; 540/316; 534/721, 638, 563, 152;
510/333; 514/2, 9; 424/76.8, 78.02, 187, 404; 536/16.8).

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated, as being drawn to different compounds of different formulae, and Inventions III and IV are unrelated, as being drawn to the method of use of the compounds Inventions I and II, respectively. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to structurally distinct compounds of two different formulae, (I) and (II). Each Invention listed above is directed to, or involves the use or making of, compounds which are recognized in the art as being distinct from one another because of their diverse chemical structures, their different chemical properties, modes of action, different effects, and reactive conditions (MPEP §§ 806.04 and 808.01). Additionally, the level of skill in the art is not such that one invention would be obvious over any of the other inventions, i.e.- they are patentable over each other. Chemical structures which are similar are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrebuttable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holdings of *Application of Papesch*, 50 CCPA 1084, 315 F.2d 381, 137 USPQ

43 (CCPA 1963) and *In re Lahu*, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are patentably distinct where the structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case one could terminate growth of a microbe with a materially different composition. The composition sulfadoxine-pyrimethamine may be administered to patients with malaria, a microbe, to terminate the growth.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case one could terminate growth of a microbe with a materially different composition. The composition sulfadoxine-pyrimethamine may be administered to patients with malaria, a microbe, to terminate the growth.

The search for each of the above inventions is not co-extensive particularly with regard to the non-patented literature search. A reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group.

Additionally, the compounds of the instant application are distinct, absent evidence to the contrary, and would require a unique search strategy. The search for the distinct compounds of each formula (I) and (II) is conducted based on their chemical structure. Therefore, the search of one chemical structure would not necessarily lead to the discovery of another structure, nor would it necessarily lead to the discovery of methods of using and/or making.

The inventions are distinct for the reasons given above and the search for one invention would not necessarily lead to the discovery of another invention. Further, because the inventions of each Group have acquired a separate status in the art as shown by their different classification, and because of the numerous classes and subclasses in each of the Groups, a serious burden is imposed on the Examiner to perform a complete search of the defined areas. Therefore, because of the reasons given *supra*, the restriction set forth is proper and not to restrict would impose a serious burden in examination of this application.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

For example, two such elections consistent with this requirement would be elections such as: Group I, A, 1- which are pharmaceutical biocides comprising compounds of formula (I) and reads upon claims 1-7 and 15-18; or Group II, C, 3- which are antibacterial household products comprising compounds of formula II and reads upon claims 19-23, 28, 29, and 33.

Election of Peptide

Claims 1-37 are generic to a plurality of disclosed patentably distinct peptide sequences comprising compounds of formulae (I) and (II). Applicant is required under 35 U.S.C. 121 to elect a single disclosed sequence of either formula (I) or formula (II) as the peptide of the invention, even though this requirement is traversed.

The election consists of election of a single 'n' value, 1-5, identification of the peptide sequence which is present, and identification of R1 and R2 (if present). *The election of a peptide sequence is not to be taken as an election of species, but rather an election of a single invention, since each peptide is assumed to be patentably distinct, in the absence of evidence to the contrary.* Further, for each invention, n = 1 to 5 would be classified in various classes and subclasses, as indicated in groups I-IV, *supra*, such

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as tripeptides are classified in class 530, subclass 531 and tetrapeptides are classified in class 530, subclass 330, while single amino acids are classified in various classes and subclasses, such as class 554, subclass 58. [Note: A formula (i.e.- formula (I) where n is 2) may NOT be elected as drawn to the elected invention because no meaningful search can be conducted without an undue burden, due to the myriad of potential substitutions possible in each permutation of each formula]. The formulae are peptides between 1 and 5 residues, lacking a substantial core from which a meaningful coextensive search could be conducted. Thus, a separate and distinct search, based on peptide sequence and structure, is required.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined and a listing of all claims readable thereon, including any claims subsequently added, even though the requirement be traversed (37 CFR 1.143).

Election of Species

Claims 1-37 are generic to a plurality of disclosed patentably distinct species comprising 'a second antimicrobial compound'. Applicant is required under 35 U.S.C. 121 to elect a single specific disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

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the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined and a listing of all claims readable thereon, including any claims subsequently added, even though the requirement be traversed (37 CFR 1.143).

Rejoinder Practice

The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

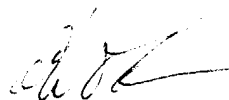
NO CLAIMS ARE ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571)272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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